U.S.S.N. 10/613,975 Filed: July 3, 2003

AMENDMENT AND RESPONSE TO OFFICE ACTION

Amendment

In the Claims

- 1. (currently amended) A vaccine composition for inducing an immune response to a pathogen comprising a nucleic acid encoding an antigen eliciting an immune response to the pathogen encapsulated in a mucoadhesive controlled release particulate formulation comprising an open-celled polymeric foam of approximately 95% void volume, or particles thereof.
 - 2. (canceled)
- 3. (currently amended) The composition of claim 2 1 further comprising a mucoadhesive polymer coating.
- 4. (original) The composition of claim 1 further comprising an enteric outer coating or capsule.
- 5. (original) The composition of claim 1 having a particulate diameter of less than five microns.
- 6. (currently amended) The composition of claim 2 1 formed by lyophilizing a solution of a biodegradable polymer to form an open-celled polymeric foam of approximately 95% void volume,

impregnating the foam with an aqueous solution of the nucleic acid, lyophilizing the foam to remove the water, and extruding the resulting matrix at ultrahigh pressures.

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7. (currently amended) The composition of claim 2 1 wherein the method further comprises cryogenically grinding the matrix to an average particle size of fifteen microns in diameter; and

sieving to isolate particles less than five microns in diameter.

- 8. (original) The composition of claim 1 wherein the polymer is a low molecular weight poly(D,L-lactide-co-glycolide).
- 9. (previously presented) The composition of claim 1 wherein the pathogen is selected from the group consisting of malaria, tularemia, anthrax, and *Helicobacter pylori*.
- 10. (original) The composition of claim 1 further comprising providing an adjuvant with the antigen.
- 11. (original) The composition of claim 1 wherein the antigen is expressed or released for a period of weeks to months.

12-21. (canceled)

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